PTO/SB/08a (08-03)
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known	
Application Number	10/650,613
Filing Date	August 27, 2003
First Named Inventor	Geenen, Vincent
Art Unit	1647
Examiner Name	
Attorney Docket Number	ULS-001.01

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No.[1]	Document Number: Number - Kind Code[2] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	US-6,197,926 B1	03/06/2001		

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[5] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	AB	Durinovic-Bello I. The Role of T Cells, MHC Molecules and Autoantigens. Autoimmunity 27:159-177 (1998)	
	AC	Griffin, A.C. et al. Experimental Autoimmune Insulitis. Induction by T lymphocytes Specific for a Peptide of Proinsulin. American Journal of Pathology 147:845-857 (1995)	
	AD	Kahn, et al. Genetics of Non-Insulin-Dependent (Type-II) Diabetes Mellitus. Annu. Rev. Med. 47:509-531 (1996)	
	AE	Dev, S.B. et al. Electrochemotherapy - a novel method of cancer treatment. Cancer Treatment Reviews 20:105-115 (1994)	
	AF	Campos, M. et al. Role of Interferon-γ in Inducting Cytotoxicity of Peripheral Blood Mononuclear Leukocytes to Bovine Herpesvirus Type 1 (BHV-1)-Infected Cells. Cellular Immunology 120:259-269 (1989)	
	AG	Alleva, D.G. et al. Immunological Characterization and Therapeutic Activity of an Altered-Peptide Ligand, NBI-6024, Based on the Immunodominant Type 1 Diabetes Autoantigen Insulin B-Chain (9-23) Peptide. Diabetes 51:2126-2134 (2002)	
	AH	Ziegler, A.G. et al. Life-Table Analysis of Progression to Diabetes of Anti-Insulin Autoantibody-Positive Relatives of Individuals With Type 1 Diabetes. Diabetes 38:1320-1325 (1989)	
	AI	Vardi, P. et al. Concentration of Insulin Autoantibodies at Onset of Type 1 Diabetes: Inverse Log-linear Correlation with Age. Diabetes Care 11:736-739 (1988)	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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Sheet	2	of	3	Attorney Docket Number	ULS-001.01

	AJ	Geenen, V. et al. The Intrathymic Expression of Insulin-related Genes: Implications for Pathophysiology and Prevention of Type 1 Diabetes. Diabetes Metabolism Reviews 14:95-103 (1998)	
	AK	Pozzilli, P. et al. No Effect of Oral Insulin on Residual Beta-Cell Function in Recent-Onset Type 1 Diabetes (the IMDIAB VII). Diabetologia 43:1000-1004 (2000)	
	AL	Dunckley, M.G. et al. Direct Retroviral-Mediated Transfer of a Dystrophin Minigene into mdx Mouse Muscle in vivo. Human Molecular Genetics 2:717-723 (1993)	
	AM	Delovitch, T.L. et al. The Nonobese Diabetic Mouse as a Model of Autoimmune Diabetes: Immune Dysregulation Gets the NOD. Immunity 7:727-738 (1997)	
	AN	Martens, H. et al. The Thymic Repertoire of Neuroendocrine Self-antigens: Physiological Implications in T-cell life and Death. Immunology Today 12:312-317 (1998)	
	AO	Semple, John W. et al. Processing and Presentation of Insulin. III. Insulin Degrading Enzyme: A Neutral Metalloendoproteinase that is Non-homologous to Classical Endoproteinases Mediates the Processing of Insulin Epitopes for Helper T Cells. International Immunology 4:1161-1167 (1992)	
	AP	Sprent, J. Central Tolerance of T Cells. Intern. Rev. Immunol. 13:5-105 (1995)	
	AQ	Wegmann, D.R. et al. Analysis of the Spontaneous T Cell Response to Insulin in NOD Mice. Journal of Autoimmunity 7, 833-843 (1994)	
	AR	Alleva, D.G. et al. A Disease-associated Cellular Immune Response in Type 1 Diabetics to an Immunodominant Epitope of Insulin. The Journal of Clinical Investigation 107:173-180 (2001)	
	AS	Liu, E. et al. Anti-peptide Autoantibodies and Fatal Anaphylaxis in NOD Mice in Response to Insulin Self-Peptides B:9-23 and B:13-23. The Journal of Clinical Investigation 110:1021-1027 (2002)	
	AT	Bonomo, A. et al. Thymus Epithelium Induces Tissue-Specific Tolerance. The Journal of Experimental Medicine 177:1153-1164 (1993)	
	AU	Czarniecki, C.W. et al. In Vitro Biological Activities of Escherichia Coli-Derived Bovine Interferons–α, -β, and -γ. Journal of Interferon Research 6:29-37 (1986)	
	AV	Geenen, V. et al. Thymic Expression of Neuroendocrine Self-Peptide Precursors: Role in T Cell Survival and Self-Tolerance. Journal of Neuroendocrinology 10:811-822 (1998)	
	AW	Chaillous, L. et al. Oral Insulin Administration and Residual β-cell Function in Recent-onset Type 1 Diabetes: a Multicentre Randomised Controlled Trial. The Lancet 356:545-549 (2000)	
	AX	Rudy, G. et al. Similar Peptides from Two β Cell Autoantigens, Proinsulin and Glutamic Acid Dearboxylase, Stimulate T Cells of Individuals at Risk for Insulin-Dependent Diabetes. Molecular Medicine 1:625:633 (1995)	
	AY	Kisielow, P. et al. Tolerance in T-cell-receptor Transgenic Mice Involves Deletion of Nonmature $CD4^+8^+$ Thymocytes. Nature 333:742-746 (1988)	
	AZ	Ragot, T. et al. Efficient Adenovirus-mediated Transfer of a Human Minidystrophin Gene to Skeletal Muscle of mdx Mice. Nature 361:647-650 (1993)	
	BA	Pugliese, A. et al. The Insulin Gene is Transcribed in the Human Thymus and Transcription Levels Correlate with Allelic Variation at the INS VNTR-IDDM2 susceptibility locus for Type 1 Diabetes. Nature Genetics 15:293-297 (1997)	
	BB	Vafiadis, P. et al. Insulin Expression in Human Thymus is Modulated by INS VNTR alleles at the IDDM2 Locus. Nature Genetics 15:289-292 (1997)	

Examiner Signature	7/21/06	Date Considered	

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	BC	Kappos, L. et al. Induction of a Non-encephalitogenic Type 2 T Helper-cell Autoimmune Response in Multiple Sclerosis After Administration of an Altered Peptide Ligand in a Placebo-controlled, Randomized Phase II Trial. Nature Medicine 6:1176-1182 (2000)	
	BD	Atkinson, M.A. The Pathogenesis of Insulin-Dependent Diabetes Mellitus. The New England Journal of Medicine 346:1685-1691 (2002)	
	BE	DPT-Type 1 Diabetes Study Group Effects of Insulin in Relatives of Patients with Type 1 Diabetes Mellitus. The New England Journal of Medicine 346:1685-1691 (2002)	
	BF	Jolicoeur, C. et al. T-cell Tolerance Toward a Transgenic β-cell Antigen and Transcription of Endogenous Pancreatic Genes in Thymus. Proc. Natl. Acad. Sci. USA 91:6707-6711 (1994)	
	BG	Greenen, V. et al. Evidence That Insulin-like Growth Factor 2 (IGF2) is the Dominant Thymic Peptide of the Insulin Superfamily. Thymus 21:115-127 (1993)	

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Examiner Name	Saoud, C.
Attorney Docket Number	ULS-001.01

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	BH	EP 0 266 057 A	05-04-1988	Merck & Co.		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	BI	~~PCT International Search Report, mailed on February 23, 2004~~. Author?	
	BJ	Geenen, et al. Role of the Thymus in the Development of Tolerance and Autoimmunity towards the Neuroendocrine System. Ann. N.Y. Acad. Sci. 992:186-195 (2003).	
	BK	Geenen, et al. Thymus tolerance dysfunction in the development of the autoimmune diabetogenic response: a way for a novel type of vaccine/immunotherapy. Diabetologia, 46:A10 (2003).	
	BL	Nakayama, et al. Prime role for an insulin epitope in the development of type 1 diabetes in NOD mice. Nature 435:220-223 (2005).	
	BM	Kent, et al. Expanded T cells from pancreatic lymph nodes of type 1 diabetic subjects recognize an insulin epitope. Nature 435:224-228 (2005).	
	BN	Skyler, J. Effects of Insulin in Relatives of Patients with Type 1 Diabetes Mellitus. The New England Journal of Medicine, 346, 22:1685-1691b (2002).	
	BO	Johnnidis, et al. Chromosomal clustering of genes controlled by the aire transcription factor. PNAS, 102, 20: 7233-7238 (2005).	
	BP	Geenen, et al. Presentation of Neuroendocrine Self in the Thymus: Toward a Novel Type of Vaccine/Immunotherapy. Drug Design Reviews - Online 1, 37-42 (2004).	
	BQ	Geenen, et al. An Insulin-like Growth Factor 2-Derived Self-Antigen Inducing a Regulatory Cytokine Profile after Presentation to Peripheral Blood Mononuclear Cells from DQ8* Type 1 Diabetic Adolescents. Ann. N.Y. Acad. Sci. 1037:59-64 (2004).	

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